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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,776	12/17/2004	Hideaki Sasagawa	TOYA107.005APC	5644

20995 7590 02/04/2010  
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EXAMINER
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JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1619

NOTIFICATION DATE	DELIVERY MODE
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02/04/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/518,776	<b>Applicant(s)</b> SASAGAWA ET AL.	
	<b>Examiner</b> Donna Jagoe	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4,8-12 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,8-12 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The indicated allowability of claim 19 in the office action dated July 27, 2009 is withdrawn in view of the newly discovered reference(s) to Itoh et al. Rejections based on the newly cited reference(s) follow.

***Claims 1, 4, 8-12 and 15-18 are pending in this application.***

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 8-12 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al. WO 97/02821 A2 and Itoh U.S. Patent No. 5,466,820A.

The claims are drawn to a pharmaceutical composition comprising the antifungal agent of figures (1) and (2) combined with (A) a film forming agent selected from *inter alia*, ethyl cellulose and (B) a water soluble plasticizer in a form of a solid or a paste at 20°C (68°F or approximately normal room temperature) at 1 atm (normal atmospheric pressure) selected from a polymer or copolymer of oxyethylene and/or oxypropylene and has a polymerization degree of 70 or more. Examples of these film forming agents and plasticizers are provided in the instant specification as "Eudragit" (film-forming agent)" and "Pluronic F68" (plasticizer).

Itoh et al. teach an antifungal agent (see abstract) comprising ethyl cellulose, hydroxypropylmethylcellulose phthalate, Pluronic F68 and Eudragit (column 12, lines 38-45). These compounds form a coating or in the case of external use, the compound can be made into solid, semisolid or liquid preparation (column 12, lines 46-49). It does not teach the specific antifungal agent of figures (1) and (2)

Kodama et al. teach the antifungal agents in figures (1) and (2) (see entire document).

It is prima facie obvious to substitute equivalents, motivated by the reasonable

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expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute the antifungal composition of Kodama et al. for the antifungal of Itoh et al. need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Addressing instant claims 9-11 drawn to the composition further comprising a surfactant, such as an anionic surfactant such as one that comprises an alkyl sulfate which may have a polyoxyethylene group and/or alkyl phosphate which may have a polyoxyethylene group, Itoh et al. does not teach this surfactant specifically, however, it discloses the dispersing agent (surfactant) Tween 80 (polysorbate 80) (column 12, line 41). It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the surfactants will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Addressing instant claim 12, drawn to an organic solvent such as acetone, Itoh et al. teach ketones such as acetone as a solvent (column 4, line 66 to column 5, line 1). Itoh et al. does not teach an antifungal composition wherein the antifungal composition is capable of "recoating" (claim 15) however, Kodama et al. teach the antifungal medicament of formula (1) and (2) for painting (page 18, example 5). It does not teach recoating, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to recoat (repaint) the formulation when necessary for treatment. Regarding the antifungal medicinal composition wherein

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the coating is removable by swelling means or physical scratching, Itoh et al. teach the coating agents Pluronic-F68 and Eudragit as a coating for oral administration. Although it does not specifically recite that the coating is removable by swelling means, one having ordinary skill in the art would readily recognize that a dosage form that is coated for enteric or sustained release properties (column 12, lines 35-38) would readily swell to release the medicament when swallowed whereby the stomach contains the aqueous solvent.

Regarding instant claim 17 drawn to the composition of instant claim 1 for an extensively keratinized portion of skin or nail or a skin-thickened portion around foot as an application target, The intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since the compositions of the patent are capable of performing the intended use of coating a foot, then it meets the claim.

It is noted that Kodama et al. and Itoh et al. do not teach the degree of polymerization of the polyoxyethylene portion of 140-180 and a polypropylene portion having a polymerization degree of 20 to 40, however, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of property inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent

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characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 4, 8-12 and 15-18 have been considered but are moot in view of the new ground(s) of rejection.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE L. EYLER/  
Supervisory Patent Examiner, Art Unit 1619

Donna Jagoe /D. J./  
Examiner  
Art Unit 1619

January 27, 2010